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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

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NOVARTIS PHARMACEUTICALS  
CORPORATION,

Plaintiff,

v.

ACTAVIS LLC; APOTEX, INC.;  
APOTEX, CORP.; GLAND PHARMA  
LTD.; DR. REDDY'S LABORATORIES,  
INC.; DR. REDDY'S LABORATORIES  
LTD.; EMCURE PHARMACEUTICALS  
USA, INC.; EMCURE  
PHARMACEUTICALS, LTD; HOSPIRA,  
INC.; PHARMACEUTICS  
INTERNATIONAL INC.; SAGENT  
PHARMACEUTICALS, INC.; ACS  
DOBFAR INFO S.A.; STRIDES, INC.;  
AGILA SPECIALTIES PRIVATE LTD.;  
SUN PHARMA GLOBAL FZE;  
CARACO PHARMACEUTICAL  
LABORATORIES, LTD; SUN  
PHARMACEUTICAL INDUSTRIES  
LTD.; WOCKHARDT USA LLC; and  
WOCKHARDT LTD.

Defendants.

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Civil Action No. 13-1028 (SDW) (MCA)

**NOVARTIS'S OPPOSITION TO WOCKHARDT'S MOTION TO DISMISS  
COUNT II OF THE CORRECTED AMENDED COMPLAINT**

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Novartis Pharmaceuticals Corporation (“Novartis”) respectfully submits this brief in Opposition to the Motion to Dismiss Count II of the Corrected Amended Complaint by Wockhardt USA LLC and Wockhardt Ltd. (collectively, “Wockhardt”).

### **PRELIMINARY STATEMENT**

This Court should deny Wockhardt’s motion, which tries to use a misguided procedural argument to avoid having to respond to Count II on the merits.

In Count II, Novartis alleges that Wockhardt and eight other generic drug maker groups are inducing or contributing to the infringement of U.S. Patent No. 8,052,987 (the “’987 patent”). That patent covers methods of treating osteoporosis and other “bone turnover” diseases with a drug invented by Novartis scientists called “zoledronic acid.” Novartis sells this drug for osteoporosis under the brand name “Reclast,” and the Count II defendants are preparing to sell, or are already selling, generic Reclast under labels that invite infringement of the ‘987 patent. Novartis has thus sued these defendants under the U.S. patent laws, 35 U.S.C. § 271.

In its motion, Wockhardt argues that Novartis’s cause of action under the ‘987 patent here duplicates a cause of action in a 2012 case in this Court, and for that reason should be dismissed. Wockhardt is wrong, for two reasons.

*First*, the claims in the two cases, while related, are hardly duplicative. This case involves additional parties, a different facts and different damages issues. Indeed, the claims in this case follow from Wockhardt’s decision to change its position with the U.S. Food and Drug Administration (FDA) months after the complaint was filed in the first case. This case simply could not have been brought in the initial 2012 pleading. Precedents cited by Wockhardt make perfectly clear that Novartis is entitled to pursue new theories based on the new facts in a new complaint.

**Second**, dismissal would only delay the inevitable. Wockhardt has confirmed to this Court that it will sell generic Reclast as soon as the FDA permits. Once Wockhardt starts to sell the drug, new damages claims will accrue to Novartis under the ‘987 patent. New claims based on actual sales would not be barred by any dismissal here. Accordingly, dismissing Count II will not remove this issue, and will cause unnecessary additional work for Novartis and the Court. If Count II is dismissed as to Wockhardt, the ‘987 patent would have to be litigated twice: first against the current non-Wockhardt defendants, and then again against Wockhardt when it begins to sell generic Reclast.

Precisely to avoid any duplication of effort, Novartis has moved to consolidate the prior Wockhardt action with this case. That motion will heard by Magistrate Judge Arleo on May 21, 2013. Consolidation, not dismissal, is the most efficient means of resolving Novartis’s related but distinct claims against Wockhardt. For that reason, the Court should deny Wockhardt’s motion to dismiss, and should consolidate the two actions together.

## FACTS

The facts here come from the Corrected Amended Complaint in this case (the “Complaint” or “Cmplt.”); the complaint and other proceedings in the first Wockhardt action; and other sources subject to judicial notice.<sup>1</sup> Relevant exhibits are attached to the accompanying declaration of Robert W. Trenchard (“Tren. Dec.”).

### **The 2012 Wockhardt Action**

Novartis’s claims under the ‘987 patent originally arose from Wockhardt’s “Abbreviated New Drug Application,” or “ANDA,” which sought permission from the FDA to sell generic Reclast. (D.I. 134, at ¶ 82.)

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<sup>1</sup> “Wockhardt/Sun Litigation” refers to *Novartis et. al v. Wockhardt et. al* (consolidated), Civil Action No. 12-cv-03967-SDW-MCA.



As part of the ANDA process, Wockhardt was required to certify to the FDA that its drug would not infringe Novartis's patent rights. (Wockhardt/Sun Litigation, D.I. 1, at ¶¶ 33-34.) Wockhardt, however, proposed to sell generic Reclast under a complete copy of Novartis's label, which includes instructions for using Novartis's patented methods to treat osteoporosis. Hence, Wockhardt could not say that it would steer clear of Novartis's patent rights. So Wockhardt instead took the position that the '987 patent is invalid in light of published literature when the application for that patent was filed. Wockhardt told the FDA and Novartis of its position in a so-called "Paragraph IV" letter on January 13, 2012, as required by the ANDA process.

Wockhardt's letter triggered Novartis's right to sue under 35 U.S.C. § 271(e), and Novartis sued in this Court on June 27, 2012, Civil Action No. 12-cv-03967-(SDW)(MCA). (Wockhardt/Sun Litigation, D.I. 1.) Wockhardt answered the complaint and asserted counter-claims on August 2, 2012. (Wockhardt/Sun Litigation, D.I. 15.) That case has since been consolidated with a related case against the Sun group of companies.

### **The Present Action**

This action involves claims under three patents related to zoledronic acid. It is being pursued against every generic drug maker planning to sell the drug, at least ten defendant groups so far. (D.I. 134, at ¶¶ 4; 7-51.) Novartis initially sought a preliminary injunction to prevent any sales in violation of Novartis's patent rights. (*Id.* at ¶ 55.) Now that some of the generic defendants have actually started selling, Novartis seeks monetary damages for Novartis's resulting financial losses.

The '987 patent is one of the three patents at issue in this case. But the theory of liability here is fundamentally different than it was in the 2012 case. The 2012 case was based on

Wockhardt's proposed sale of generic Reclast under a full copy of Novartis's label, including uses to both osteoporosis and Paget's disease. This case, however, is not.

On September 18, 2012, three months after Novartis filed the 2012 case, Wockhardt filed a different proposed label that apparently omits all uses of zoledronic acid to treat osteoporosis. Called a "Section viii" filing, Wockhardt's new proposed label provides an indication solely for treating a condition called "Paget's disease," which Wockhardt contends is not covered by the '987 patent. Wockhardt first disclosed its revised position to Novartis in a document production on the evening of October 2, 2012, in which it produced its revised FDA filing. (Tren. Dec. Ex. 1.)

But as set out in the Complaint in this action, Wockhardt and the other generics (who have submitted similar labels) cannot avoid the '987 patent so easily. The generics' Section viii letters to the FDA are a transparent sham, designed to exploit a perceived loophole in the ANDA process. Contrary to the proposed labels, all of the defendants still intend to sell generic Reclast to treat osteoporosis. Anything else would be economically irrational. Only about 1,000 Paget's patients were treated with Reclast last year, and only one dose of the drug is required to send the condition into remission. Inasmuch as generic Reclast is expected to sell for about \$100 per dose, only a crazy generic drug maker would actually seek to limit sales of Reclast to Paget's patients. Sales to these patients would not even cover the cost of bringing the drug to market. (D.I. 134, at ¶¶ 72-73.)

The facts showing Wockhardt's agenda in particular are especially stark. As shown by its initial Paragraph IV position, Wockhardt planned from the outset to sell generic Reclast to osteoporosis patients, in direct conflict with the '987 patent. Wockhardt's Paragraph IV letter attacked the '987 patent as being invalid, in order to permit Wockhardt to sell generic Reclast

with a label covering all uses of the drug. Consistent with that plan, Wockhardt spent five years and \$500,000 to prepare to bring generic Reclast to market. (D.I. 57-7, at ¶¶ 4-5.) Then, at the last minute, Wockhardt changed gears and proposed selling under a Paget's-only label. But it still made over 26,000 doses of the drug and procured material to make 50,000 doses—far more than necessary for the tiny Paget's patient population. (*Id.* ¶ 8.) The only rational explanation for Wockhardt's behavior is that it intends to sell generic Reclast for treatment of osteoporosis, in violation of the '987 patent.

That agenda exposes Wockhardt to liability for inducing or contributing to the infringement of the '987 patent, under 35 U.S.C. § 271(b), (c) and (e). Moreover, because the generics have or will be selling generic Reclast in the same time period, they will be jointly and severally liable for the resulting price drop and effect on Novartis, as shown below.

#### **Wockhardt's Efforts To Avoid The Merits**

Perhaps because the facts showing Wockhardt's intentions are so damning, it has been especially desperate in looking for a way to avoid having to defend its conduct on the merits.

For instance, Wockhardt has opposed Novartis's motion to amend its asserted claims in the initial action under the Local Patent Rules, to add claims from the '987 patent. Even though that patent has always been in the case, Wockhardt contends that Novartis's attempt to add claims from that patent is barred as untimely under the Local Patent Rules. This motion is fully briefed and set for oral argument before Magistrate Judge Arleo on May 21, 2013. (April 9, 2013 Text Order.)

In the present motion, Wockhardt is also trying to sidestep claims against it under the '987 patent. Wockhardt's premise is that this action is supposedly "duplicative" or "the same" as the initial action. However, Wockhardt ignores the different parties, different theories and

different damages issues in the two cases. Wockhardt also fails to explain how dismissal would be efficient in light of Wockhardt's impending launch of generic Reclast, and the new claims that would result from that launch. For these and other reasons addressed below, Wockhardt's motion should be denied.

### **ARGUMENT**

Under Civil Rule 12(b)(6), a motion to dismiss should be denied "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Johnsrud v. Carter*, 620 F.2d 29, 33 (3d Cir. 1980) (citation omitted). "The defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). "Since the long-established federal policy of civil litigation is to decide cases on the proofs, district courts generally disfavor Rule 12(b)(6) motions." *Caldwell Trucking PRP Group v. Spaulding Composites, Co., Inc.*, 890 F. Supp. 1247, 1252 (D.N.J. 1995) (citing *Melo-Sonics Corp. v. Cropp*, 342 F.2d 856 (3d Cir. 1965)).

These principles require that Wockhardt's motion be denied. The differences between this case and the 2012 action preclude dismissal, especially because those differences are based on events that post-date the 2012 Wockhardt complaint. Dismissal would also be a waste time, given Wockhardt's stated intent to sell Reclast upon receiving FDA approval. This Court instead should consolidate the 2012 case with this action so that the many issues that do overlap can be resolved in the most efficient manner possible.

**I. Count II In This Action Should Be Allowed To Proceed Because It Is Not Duplicative Of The 2012 Action**

Wockhardt relies upon the “claim splitting” doctrine for its attack on the Complaint in this case.<sup>2</sup> As Wockhardt points out in its brief, claim-splitting rules are similar to claim-preclusion rules, which prohibit relitigation of decided claims. (Wockhardt Br. at 5 (citing *Katz v. Gerardi*, 655 F.3d 1212, 1219 (10th Cir. 2011).) Both types of rules are targeted at preserving judicial resources by precluding duplicative suits. But Wockhardt is wrong in arguing that these rules would preclude the present action. This case is too different from the 2012 case for the claim-splitting rules to apply.

A case Wockhardt cites twice, *Curtis v. Citibank, N.A.*, 226 F.3d 133, 139 (2d Cir. 2000), makes clear that claim-splitting is not implicated where, as here, a second complaint is based on “events arising after the filing of the complaint that formed the basis of the first lawsuit.” *Curtis*, 226 F.3d at 139. When new events occur, they need not be added to the first case through a motion to amend. Instead, “[t]he crucial date is the date the complaint was filed. The plaintiff has no continuing obligation to file amendments to the complaint to stay abreast of subsequent events; *plaintiff may simply bring a later suit on those later-arising claims.*” *Curtis*, 226 F.3d at 139 (emphasis added). The Third Circuit has adopted the rule of *Curtis* in *Schneider v. United*

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<sup>2</sup> Oddly, Wockhardt also cites *Colo. River Water Conservation Dist. v. U.S.*, 424 U.S. 800 (1976), as a basis for dismissal. (Wockhardt Br. at 5.) But *Colorado River* has no application here. That case involved dismissing a duplicative federal lawsuit in favor of a parallel state action in order to vindicate the policies of a particular federal statute, the McCarran Amendment. *Colorado River*, 424 U.S. at 806. That basis for dismissal has no relevance in this case.

*States*, 301 Fed. Appx. 187 (3d Cir. 2008), and Third Circuit law controls issues like this.<sup>3</sup> *Curtis* accordingly governs this action, as Wockhardt apparently acknowledges in relying on the case in its brief.

In *Curtis*, the Circuit held that it was an abuse of discretion for the district court there to dismiss a second-filed case, and so it would be here. With respect to Wockhardt, Novartis has followed exactly what *Curtis* says is a proper procedure: it has brought a new complaint based on events that occurred after the initial June 27, 2012 complaint against Wockhardt. The claims in the present action arise out of Wockhardt's September 20, 2012 Section viii carve-out letter with the FDA—filed three months after the initial complaint against Wockhardt. Thus, on a straightforward application of *Curtis*, this case should proceed.

Wockhardt puts great weight on a clause in Novartis's letter brief in support of amending the initial case to add-in claims from the '987 patent. (Wockhardt Br. at 1, 3.) While the reason Wockhardt cites the clause is not entirely clear, it appears to contend that the clause is evidence of the duplicativeness of the two cases. It is not. To begin with, the clause is mistaken in saying that the '987 patent is not asserted in this action against Wockhardt, as is apparent from the face of our initial and reply letter briefs in our motion to amend the initial case.<sup>4</sup> More importantly,

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<sup>3</sup> See *Yip v. Hugs to Go LLC*, 377 F. App'x 973, 976 (Fed. Cir. 2010) ("Under the law of the applicable regional circuit, here the Third Circuit, the assertion of res judicata by a party to the prior proceeding is entitled to plenary review."); *Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1323 (Fed. Cir. 2008) ("To the extent that a case turns on general principles of claim preclusion, as opposed to a rule of law having special application to patent cases, this court applies the law of the regional circuit in which the district court sits—here the Ninth Circuit.").

<sup>4</sup> The same letter that contains the clause also says that "Novartis notes that it has filed a separate suit against Wockhardt ... relating to the ... '987 ... patent[]." (D.I. 51, at n.6.) Similarly, the reply letter brief says that the '987 patent is "before the Court in the newly-filed case against Wockhardt and other generics." (D.I. 55, at n.2; see also n.3.) So the clause on which Wockhardt relies so heavily was simply a mistake, as proven conclusively by the Complaint in this case itself.

the complaints and surrounding facts in the two actions speak for themselves—the cases, while overlapping in some respects, are not duplicative.

To be sure, the present action concerns the same patent as the initial action against Wockhardt. But *Curtis* cautioned that “[a] court must be careful ... not to be swayed by a rough resemblance between the two suits[.]” When the claims are “not *entirely duplicative*,” then “dismissal [would be] inappropriate[.]” *Curtis*, 226 F.3d at 136 (emphasis added). The claims here under the ‘987 patent are nowhere close to “entirely duplicative” of and are not based on “the same facts” as those in the first action against Wockhardt. They differ in at least the following respects:

1. This case has different though overlapping parties: Novartis is suing eight different generic defendant groups for infringing the ‘987 patent. But the initial Wockhardt action involved only two generic drug makers. This difference goes to the heart of the claim-splitting doctrine, which is mainly intended “to foster judicial economy” *Curtis*, 226 F.3d at 138 (quoting *Kerotest Mfg. Co. v. C-O-Two Fire Equipment Co.*, 342 U.S. 180); *see also* Wockhardt Br. at 5 (citing “judicial economy” as the first objective of the claim-splitting doctrine).

Due to the other defendants here, this Court will still have to resolve Novartis’s claims under the ‘987 patent regardless of how it resolves this motion. Novartis will continue to press its claims against the remaining defendants whatever the outcome here. As a result, dismissing the case against Wockhardt will yield no efficiency benefits for the Court. This fact alone warrants denial of Wockhardt’s motion.

2. This case has a different theory of liability: Unlike the first case, in this case Novartis pursues a sham label theory of liability that arose from Wockhardt’s actions after the

date of the 2012 complaint. That theory raises issues not present in the first action, such as the following:

- The Court here will have to address whether Wockhardt's sham Section viii filing with the FDA can support a cause of action under 35 U.S.C. § 271(e). That exact issue is currently being briefed in connection with motions to dismiss by other defendants in this case. (D.I. 209, 219.)
- The Court here will have to assess whether Wockhardt actually intends to limit its sales of sell generic Reclast to Paget's plaintiffs, or instead whether Wockhardt's true intent is to induce doctors to prescribe generic Reclast to osteoporosis patients in violation of Novartis's patent rights.
- The Court here will have to assess whether sales targeted at Paget's disease are a "substantial non-infringing use" and thus a defense to the contributory infringement under 35 U.S.C. § 271(c), as several defendants contend in recently-filed motions to dismiss. (D.I. 207, 209.)

None of these or related issues are (or could have been) implicated in the original 2012 complaint against Wockhardt. Wockhardt nonetheless claims that this action amounts to "vexatious ... concurrent litigation over the same subject matter." (Wockhardt Br. at 5.) While some issues in this case will surely overlap with issues in the 2012 action against Wockhardt, such overlap alone is insufficient. *Curtis* requires "absolute duplication" to dismiss an action as duplicative. As another district court and this Circuit has held, even cases with "many similarities between the allegations" do not implicate the claim splitting rules when "the operative events at issue" in the second complaint "occurred well after the date" of the first



complaint. *Leonard v. Stemtech Intern., Inc.*, 2012 WL 3655512, at \*8-9 (D. Del. Aug. 24, 2012).

Against this backdrop, Wockhardt's accusations of "gamesmanship" by Novartis ring hollow.<sup>5</sup> (Wockhardt Br. At 3.) Novartis is suing different parties on a different theory of liability for a different form of relief. That is not "gamesmanship." If anything, it is Wockhardt that is engaging in gamesmanship in its misuse of the ANDA process to secure a sham label—a fact that must be treated as true on this motion to dismiss. In that connection, "the district court [should] consider the equities of the situation when exercising its discretion" in the claim-splitting setting. *Curtis v. Citibank, N.A.*, 226 F.3d 133, 138 (2d Cir. 2000). Here, Wockhardt's own gaming of the ANDA process cuts strongly against Wockhardt's motion.

3. This case has different damages issues: Finally, this case raises damages issues not present the first case against Wockhardt.

In this case, Novartis seeks to recover damages caused to it by the sale of Reclast and Zometa in contravention of its patent rights. In the case of multiple generic launches, joint and several liability is appropriate in such circumstances because declining prices cannot be easily attributable to any single defendant. Such liability is available for tortious conduct where each party contributes to "a single and indivisible harm to the injured party." Restatement (Second) of Torts § 875 (1979). The price drop precipitated by the generic defendants' collective entry to the market may be just such an indivisible harm to Novartis. As a result, including all of the parties

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<sup>5</sup> Wockhardt cites the Court's statements in its oral ruling on Novartis's motion for a temporary restraining order in support of its accusations of "gamesmanship." (Wockhardt Br. at 3.) We respectfully disagree with the Court's statements in that regard. But whatever their application to Novartis's request for a temporary restraining order, they are of no bearing here in a motion to dismiss. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395 (1981) ("the findings ... made by a court [on] a preliminary injunction are not binding ... on the merits[.]").

who have launched a particular generic product in a single case makes sense. Novartis could not have done that when the 2012 case was filed.

Wockhardt has no answer to any of these differences between this case and the 2012 case. Indeed, Wockhardt does not mention these differences at all, preferring instead to pretend that the two cases are exactly the same. (*See* Wockhardt Br. at 5.)<sup>6</sup> Wockhardt does argue that permitting this suit to go forward would allow Novartis to avoid the process of amending its claim disclosures in the original case. (*Id.* at 9.) This argument is wrong. Novartis is currently pursuing such an amendment. However, even if the Court were to deny the amendment of those disclosures and then further dismiss the ‘987 patent from that case, such a dismissal would not be on the merits. Novartis will thus be allowed to pursue its claims under the ‘987 patent regardless of how the motion to amend is decided.

The Federal Circuit recently made this clear in *Frolow v. Wilson*, 2013 WL 1007716 (Fed. Cir. Mar. 15, 2013). In *Frolow*, the district court had granted summary judgment in a patent case in part because the plaintiff had not timely disclosed certain products at issue. The Federal Circuit reversed, holding that a failure to timely identify the products would not be a basis for a “judgment on the merits.” Rather, only “dismissal” *not* on the merits—*i.e.*, without prejudice—might be appropriate. That ruling is consistent with the federal courts’ general policy

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<sup>6</sup> In that regard, the cases Wockhardt cites in which a court has dismissed a second-filed actions as duplicative all involve instances where the second case was virtually identical to the first action, unlike this case. For instance, in *Unitronics, Inc. v. Robotoc Parking Systems, Inc.*, 2010 WL 2545169 (D.N.J. Jun. 18, 2010), which Wockhardt cites on page five of its brief, the two cases at issue concerned exactly the same question: whether one party could gain access to the other party’s documents. *Id.* at \*2-3. And in *Walton v. Eaton Corp.*, 563 F.2d 66 (3d Cir. 1977), the claims in the two cases were “identical.” (Wockhardt Br. at 5.) The same is true in *Katz v. Gerardi*, 655 F.3d 1212 (10th Cir. 2011), cited by Wockhardt at page five of its brief. In that case, the Tenth Circuit said that dismissal under the claim splitting doctrine requires that the second case “be founded upon the same facts” as the first case. *Id.* at 1217 (quoting *The Haytian Republic*, 154 U.S. 118, 124 (1894)).

of resolving claims on their merits,<sup>7</sup> and of making dismissals for procedural defaults “without prejudice.”<sup>8</sup>

Since any dismissal in the initial Wockhardt case will necessarily be without prejudice, it will have no preclusive effect here. *Res judicata* requires a “a final judgment *on the merits* in a prior suit,” *Aldrich Nine Assoc. v. Foot Locker Specialty, Inc.*, 2009 WL 74401, at \*3 (3d Cir. Jan. 13, 2009) (emphasis added). Again, *Curtis* is instructive: “[D]enial of a motion to amend will not inevitably preclude subsequent litigation of those claims set out in a proposed new complaint .... Only denial of leave to amend *on the merits* precludes subsequent litigation of the claims in the proposed amended complaint.” *Curtis*, 226 F. 3d at 139; *see also Venuto v. Witco Corp.*, 117 F.3d 754, 760 (3d Cir. 1997) (denial of motion to amend without prejudice preserves plaintiff’s ability to bring second suit).

## **II. Dismissing Count II Would Be Pointless And Counter-Productive**

Even if, contrary to fact, the instant case were the same as the prior 2012 case against Wockhardt, dismissal would not be an appropriate exercise of the Court’s discretion. [REDACTED]

[REDACTED]

[REDACTED]

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<sup>7</sup> “It is well settled that the preference of the Third Circuit is to decide cases on the merits.” *N’Jie v. Cheung*, 2010 WL 3259793 (D.N.J. Aug. 16, 2010) (citing *Medunic v. Lederer*, 533 F.2d 891, 893–94 (3d Cir.1976)). As the Third Circuit noted in *Medunic*, “we have long indicated our preference that cases be decided on their merits.” *See also Hritz v. Woma Corp.*, 732 F.2d 1178, 1181 (3d Cir.1984) (noting that “we have repeatedly stated our preference that cases be disposed of on the merits whenever practicable”); *Sharp Kabushiki Kaisha v. Thinksharp, Inc.*, 448 F.3d 1368, 1372 (Fed. Cir. 2006) (stating a policy that “decision to permit [] litigation is favored,” and that dismissal on procedural grounds is disfavored; “precedent weighs heavily against denying litigants a day in court unless there is a clear and persuasive basis for that denial”).

<sup>8</sup> The Third Circuit held that procedural dismissals should be without prejudice in *Walton v. Eaton Corp.*, 563 F.2d at 70-71, one of the cases on which Wockhardt relies on this motion.

Once Wockhardt actually starts selling Reclast, new claims for damages will accrue to Novartis that could not have been asserted earlier. And claims that could not have been asserted at the time a prior action is dismissed will not be barred by claim preclusion.

In particular, 35 U.S.C. § 271(e)(4)(C) provides that damages claims may be made “only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product[.]” *See also Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, Civil Action No. 91-3423, 1991 WL 267892 (D.N.J. Dec. 12, 1991) (money damages claim available only upon actual sale). Accordingly, Novartis would be unable to assert a damages claim against Wockhardt until it actually begins selling generic Reclast, which had not occurred prior the complaint in this action being filed.

As shown above, under *Curtis*, the date of the complaint controls whether a claim would have been asserted in a prior action. (*Supra* at 7.) Hence, because damages claims could not have been asserted in the initial 2012 complaint, they will not be precluded in this action. See *Crossroads Cogeneration Corp. v. Orange & Rockland Utilities, Inc.*, 159 F.3d 129, 140 (3d Cir. 1998) (district court erred in applying claim preclusion where certain claims were unavailable to plaintiff in the first-filed action); Restatement (Second) of Judgments § 26(1)(c) (claims not precluded where “plaintiff was unable to rely on a certain theory of the case or to seek a certain remedy or form of relief in the first action because of the limitations on the subject matter jurisdiction of the courts or restrictions on their authority to entertain multiple theories or demands for multiple remedies or forms of relief in a single action, and the plaintiff desires in the second action to rely on that theory or to seek that remedy or form of relief...”)

Given these realities, there is no practical benefit to dismissing this action as Wockhardt maintains. Dismissal will only make the job of litigating this case more difficult, as the other defendants litigate the '987 patent against Novartis, and Wockhardt waits on the sidelines until it actually starts selling generic Reclast. Dismissal here would thus create the risk that the Court would have to resolve issues concerning the '987 patent twice, once on the claims against the non-Wockhardt defendants, and then again in a separate damages action against Wockhardt. Nothing in the claim splitting doctrine requires such an absurd result.

### **III. This Case Should Be Consolidated With The Prior 2012 Action Against Wockhardt**

While this case is different than the 2012 litigation, it does contain some overlapping issues regarding the scope and validity of the '987 patent. These similarities show that consolidation, not dismissal, is the appropriate way to manage these cases.

Novartis's consolidation briefs speak for themselves and will not be rehashed here. However, we note that one of the cases featured in Wockhardt's brief (at 5), *Walton v. Eaton Corp.*, 563 F.2d 66, 71 (3d Cir. 1977), is of accord. *Walton* holds in the context of a claim-splitting argument that, "[w]hen a court learns that two possibly duplicative actions are pending on its docket, consolidation may well be the most administratively efficient procedure. If the second complaint proves to contain some new matters, consolidation unlike dismissal of the second complaint without prejudice or staying the second action will avoid two trials on closely related matters." So it is here, and the Court should consolidate this action with the existing action against Wockhardt.

### **CONCLUSION**

For the foregoing reasons, Wockhardt's Motion to Dismiss Count II should be denied.

DATED: May 6, 2013

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**CERTIFICATE OF SERVICE**

I hereby certify that all counsel of record are being served via electronic mail and/or the ECF system with a copy of the foregoing Novartis's Opposition to Wockhardt's Motion to Dismiss Count II of the Corrected Amended Complaint and Declaration of Robert W. Trenchard in Support of Novartis's Opposition to Wockhardt's Motion to Dismiss Count II of the Corrected Amended Complaint on May 6, 2013.

DATED: May 6, 2013

s/ William J. O'Shaughnessy  
William J. O'Shaughnessy